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PATENT- OCH REGISTRERINGSVERKET
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This invention is concerned with the measuring of the amount of red blood cells in blood or the like. When administrating blood to a person that has lost blood or who is operated on, or whose blood is undergoing dialysis, it is important to monitor the amount of red blood cells, since too low or too high numbers can be dangerous and maybe even fatal. Also, it is of essence to know the red blood cell count of a donors' blood. The measuring methods and apparatuses existing today are either not suited for continuous monitoring or too inaccurate to provide an efficient and accurate control basis. Prior art attempts to use the well know Lambert-Beer principle of attenuation. This – however – can only be used when the blood is in near contact with the light emitter and the light detector, such as in a laboratory photometer. Also, attempts have been made to compensate unlinear effects.

When administrating blood, it is of great value if the action of extraction of blood from tubings, blood transport devices, cuvettes or the like, can be avoided. This would save time, cost, blood and also enhance safety for the personnel.

In view of the above indicated problems it is the object of the invention to define a measuring method and an apparatus allowing continuous, safe and sufficiently precise measuring of the red blood cell count.

In accordance with the invention, the above object is achieved by radiating the blood with, preferably, near infrared light (NIR) and measuring the light scattered by the blood cells in at least two essentially oppositely angled directions relative the direction of the entering illuminating light beam; preferably at a right angle.

Practical tests have shown that a remarkable improvement in precision relative the prior art is achieved already when only two exit directions are monitored, although precision increase with the number of detectors. Also, an arrangement with a plurality of perpendicularly arranged emitters and a plurality of relative each other perpendicular detectors offset in the stream direction will provide good results.

The invention is surprisingly simple and yet accurate. One reason for the successful measuring with the invention is that the red blood cells act as minute reflectors. It is well known that red blood cells scatter and refract light. The blood cells having a normal orientation essentially perpendicular to the plane defined by the sensors and the light source will to a sufficient extent either be directed into one detector or the opposite one. These facts contribute to the explanation of the surprisingly good results achieved

with the invention as compared with those of previous optical attempts.

The quality of the invented measuring method is shown in fig. 1, where in a diagramm the correlation between measurements taken in accordance with the invention of prepared samples and careful laboratory reference measurements of the same samples is shown.

The blood cell flow may be randomly spread, randomly oriented and randomly concentrated due to flow characteristics varying from set up to set up. For instance, a slightly changed bend of the pipe a distance away from the measure point may cause a change in the flow, thus offsetting the concentration core of the blood cells flowing past the sensors. By increasing the number of sensors to cover reflections from an as large part as possible of the flow cross section, such variations may be further reduced in the measuring. Also, an arrangement with one or several additional sets of emitters at other angular directions together with corresponding sensors can improve the accuracy of the measuring. The different emitters may be pulsed so that they do not influence each others derived signals. Still, the pulses may be so frequent that the location of the blood cells is practically the same from one said pulse to the next.

In accordance with the invention, the clamping sensor part has a polygonal cross section, in particular triangular, rectangular or quadratic. This provides a number of advantages: Good contact with the elastic tubing is obtained even if the dimensions of this vary. By arranging the sensors in the flat parts of the clamps uninfluenced conditions for the sensors will be obtained from occasion to occasion. Additionally the area of the cross section will be slightly decreased increasing the speed of the blood cells. Also, the flow in the corners will be somewhat slowed down. In all, the flow variations caused by outer circumstances is compensated for, as apparent in the description.

Also, the optical coupling is well defined by the possibility to have a short air space from the sensor or illumination source to the pipe. Nor is it necessary to apply special gel coupling substances between the tubing and the emitters and sensors respectively.

Further advantageous features and advantages of the invention are apparent from the claims as well as the following description of an embodiment of the invention shown in the enclosed drawing. Fig 1 is a diagram showing the correlation between measurements taken in accordance with the invention of prepared samples and careful

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laboratory reference measurements of the same samples, fig 2 show a cross section of a device according to the invention, and fig 3 and 4 a similar embodiment of the invention.

The measuring unit in the in fig 2 consists of a U-shaped channel 1 in the bottom 2 and sides 3, 4 of which plates 5, 6, 7 are arranged each provided with a row of holes or openings 8 along the channel. In the bottom plate 6 a light emitter 10 is arranged in the first hole in the row. In the plates located on the sides of the channel the plates light sensors 9 are arranged in the first the holes (in the same end as the light emitters. The emitters 10 and the sensors 9 are all arranged at the outer end of the holes on the panel sides facing away from the center of the channel. The sensors and emitters are directed towards the center of the channel.

The channel is further provided with a lid 11 with which the channel can be covered transferring it to a tube-like structure with a square cross section. Also the lid 11 is provided with a hole provided plate 12 with a sensor 9 or emitter 10 at the outside of each hole.

In other holes in the four said rows of holes, detectors or emitters can be fitted for further enhancement. If detectors or emitters in these said other holes, the holes at the ends of the rows can be fitted with detectors or emitters with no limit to selection other than that at least one emitter is used in the measuring unit.

The embodyment shown in fig 3 and 4 is similar to that of fig 2 and the same reference numerals is therfor used.

When red blood cell measuring is to take place, an elastic clear tubing 13, that is used anyway for the blood transport to or from a patient, is placed in the channel 1. The lid 11 is put in place, pressed down against the tubing 13 and then locked in place. The size of the channel in its closed form is at fabrication chosen so small that the plastic tubing at clamping is forced to assume an essentially square cross section with slightly rounded corners. The emitted light intersects the area from which the sensors can detect light scattered towards the sensors resulting in a "scanned area " 14.

A further developed embodiment may include the possibility to adjust the size of the channel with lid.

The channel and lid is not limited to the shape of a "U" and lid, but can also, for instance be shaped as two equally formed "L-s" or two opposed angular elements.

The use of a rectangular channel has the advantage that several parallel

sensors may be arranged in the same plane and sense the presence of red blood cells in an increased cross section area where emitted light can be sensed.

Due to the compression of the clear tubing this will bulge out slightly into each hole in the plates forming lens-like surfaces that will help in focusing a broader beam of scattered light to the sensors. Since however the wall of the tubing in front of the light sources and sensors is essentially flat, the light transport laterally into or out from the tubing through its wall will be reduced in relation to circular tubing, thus essentially eliminating an error source. Also the sharp corners will work in this direction since light propagation is reduced in a circumferential direction.

While measuring, short light pulses with a suitable wavelength are emitted from the light sources and then measured by the sensors. The signals from the sensors are fed to an evaluation device, for instance a computer or signal processor, where the signals are integrated, summed or processed in other ways in order to provide a measure representative of the entire amount of red blood cells in the tubing. From this result, the hematocrit value can be expressed as shown in fig. 1.

It has turned out that already by using only two perpendicular sensors very accurate values are obtained. Additional certainty and precision can be achieved by using more emitters, and/or sensors. Presumably further precision can be gained by disruption of the square cross section or a change to another cross section or the same but slightly angled.

A considerable advantage of the invention is that no special measuring chamber has to be separately fabricated, exchanged or washed.

By using two wavelengths measuring also the oxygen saturation and other blood constitutions can be measured.

A great advantage is that a measuring device is obtained that can simply be clamped around a present clear tube without the tubing wall curvature influencing the measuring.

Several light sources may be used causing the blood cells in a defined area or space to reflect light to the sensors.

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PATENTKRAV

1. Apparatus for the measuring of the amount of red blood cells in a sample, characterized in that it comprise a reception space for the reception of a section of a tubing for a blood flow, said reception space being polygonal, in particular square to its cross section and so dimensioned relative the tubing that the cross section of this when clamped in the reception space becomes at least slightly polygonal.

2. Apparatus according to claim 1, characterized in that the reception space is constituted of a square U-shaped enclosing channel with a lid.

3. Apparatus according to claim 1, characterized in that the reception space is constituted of an enclosing channel formed by two L-shapes.

4. Apparatus according to claim 1,2 or 3, characterized in that sensors or light sources are arranged in the flat areas of the tubing.

5. Apparatus according to claim 4 characterized in that openings are arranged in the flat walls of the reception space for the arrangement of sensors and light sources.

6. Apparatus according to claim 5, characterized in that an air space is left between the tube wall and the sensors as well as the light source.

7. Apparatus according to claim 1, characterized in that it comprises a light source and at least two essentially opposite sensors.

8. Apparatus according to claim 7 characterized in that sensors and light source are arranged perpendicular to the direction of a tubing for a blood stream to be.

9. Apparatus according to claim 7 characterized in that sensors or light sources are arranged in the flat areas of the tubing.

10. Apparatus according to claim 9 characterized in that openings are arranged in the flat walls of the reception spaces for the arrangement of sensors and light sources.

11. Apparatus according to claim 10, characterized in that an air space is left between the tube wall and the sensors as well as the light source.

SAMMANDRAG

Apparatus a for the measuring of the amount of blood cells in a sample, comprising a reception space for the reception of a piece of a tubing for a blood flow, which reception space is polygonal, in particular square, to its cross section and so dimensioned relative the tubing that the cross section of this when clamped becomes at least slightly polygonal. The reception space is constituted of an enclosing channel and sensors and light sources are arranged in the flat areas of the tubing.

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Fig. 1

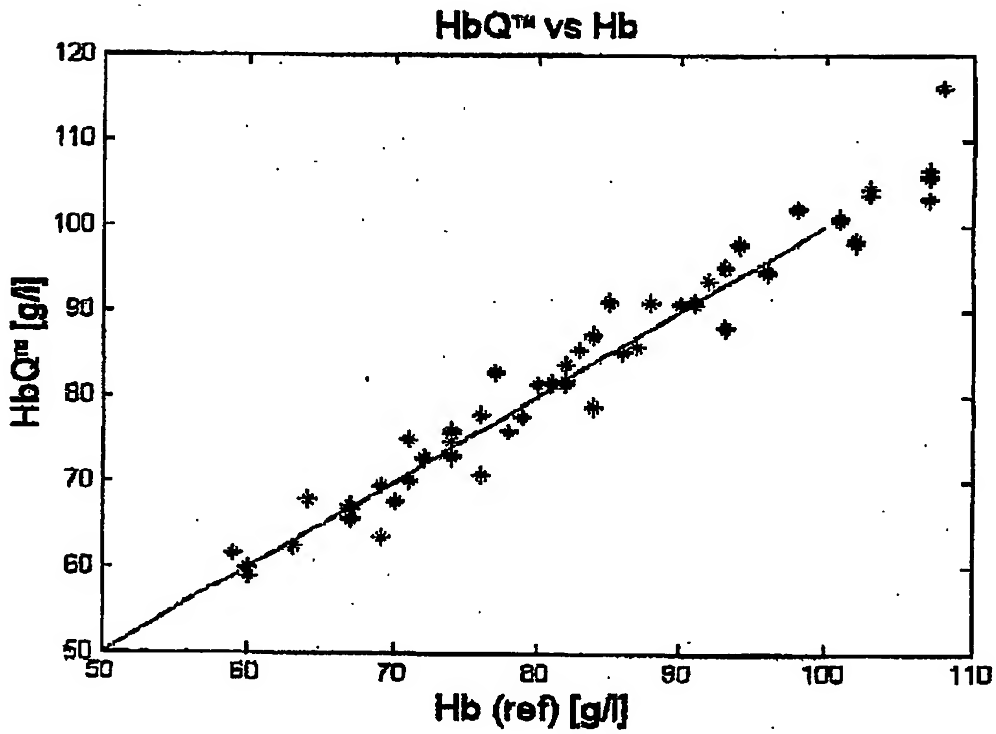

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Fig. 2

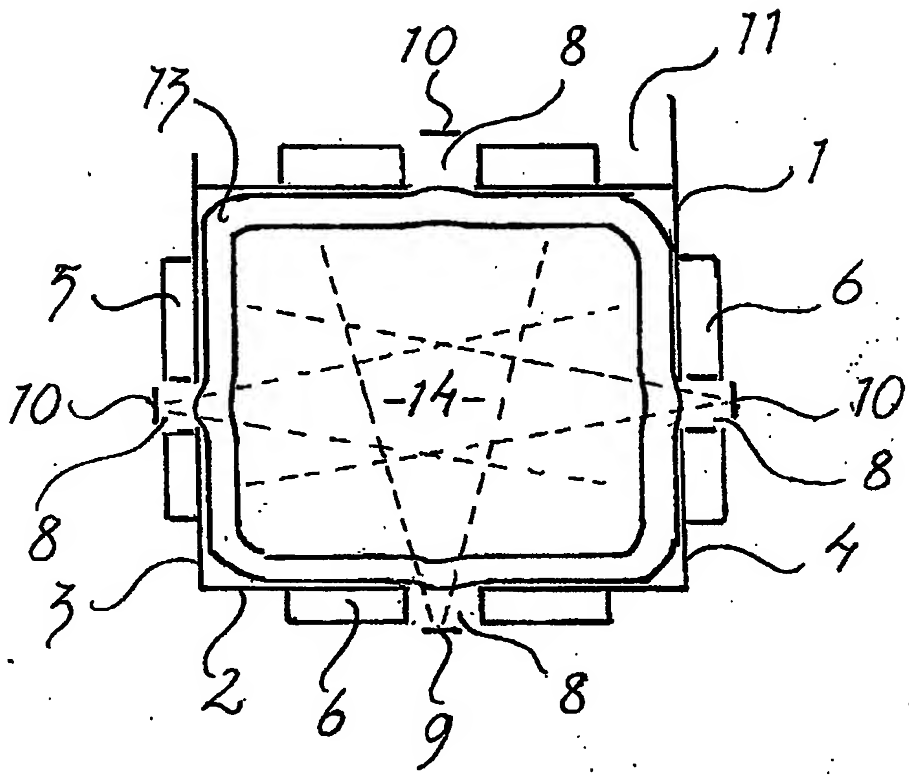

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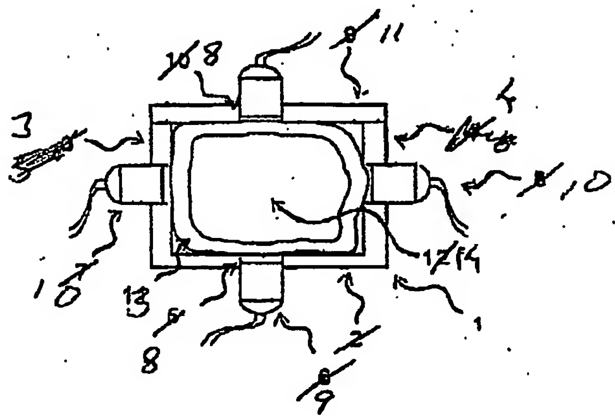
Figure ~~1~~ 3



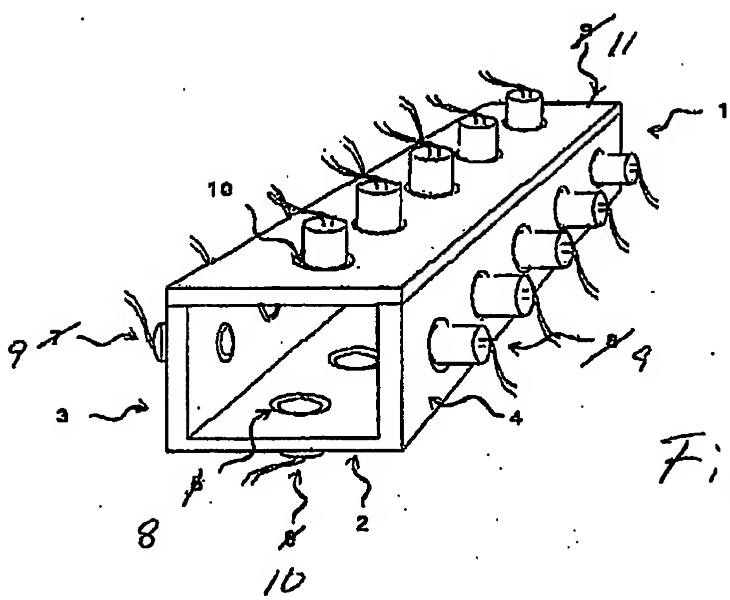


Fig 4